

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Apotex, Inc. and Apotex Corp. (“Apotex” or “Defendants”).

1. This is an action by Cephalon against Apotex for infringement of U.S. Patent Nos. 8,445,524 (“the ’524 patent”), 8,436,190 (“the ’190 patent”), 8,609,863 (“the ’863 patent”), 8,791,270 (“the ’270 patent”), 8,669,279 (“the ’279 patent”), 8,883,836 (“the ’836 patent”), and 8,895,756 (“the ’756 patent”). This action arises out of Apotex’s filing of its Abbreviated New Drug Application (“ANDA”) No. 204230 (“Apotex’s ANDA”) seeking approval by the U.S. Food and Drug Administration (“FDA”) to sell generic versions of TREANDA[®], Cephalon’s innovative drug for the treatment of patients with chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’524, ’190, ’863, ’270, ’279, ’836, and ’756 patents.

THE PARTIES

PLAINTIFF CEPHALON, INC.

2. Cephalon is a corporation operating and existing under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon is

engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

DEFENDANTS APOTEX, INC. AND APOTEX CORP.

3. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

4. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

6. On information and belief, Apotex Corp. serves as Apotex Inc.'s United States sales agent and distributor for generic pharmaceuticals, which it distributes in the State of Delaware and throughout the United States. On information and belief, Apotex Inc. conducts its North American operations, in part, through Apotex Corp. On information and belief, together, Apotex Inc. and Apotex Corp. collaborate in the manufacture, marketing, and sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved Abbreviated New Drug Applications) within the United States generally, and the State of Delaware specifically.

JURISDICTION AND VENUE

SUBJECT MATTER JURISDICTION

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202.

PERSONAL JURISDICTION

9. On information and belief, this Court has personal jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in Delaware and therefore subject to the jurisdiction of this Court. As a domestic corporation, Apotex Corp. is registered to do business with the Delaware Department of State Division of Corporations. Furthermore, Apotex Corp. markets and sells generic drugs within the State of Delaware and throughout the United States. On information and belief, Apotex Corp. avails itself of the benefits and protections of the laws of the State of Delaware. For example, upon information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy pursuant to 24 Del. C. § 2540. On information and belief, Apotex Corp. has appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

10. On information and belief, this Court has personal jurisdiction over Apotex Inc. because Apotex Inc.: (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum through its wholly owned subsidiary Apotex Corp. by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell or sell, Apotex Inc. pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Apotex Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA[®] for sale and use throughout the United States, including the State of Delaware.

11. This Court also has personal jurisdiction over Apotex Inc. under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law and, on information and

belief, Apotex Inc., as a Canadian company, is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over Apotex Inc. is consistent with the Constitution and the laws of the United States.

12. On information and belief, this Court also has personal jurisdiction over Apotex because Apotex previously has been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Otsuka Pharmaceutical Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 15-109 (D. Del.); *Aptalis Pharmatech, Inc. & Ivax International GmbH v. Apotex Inc. & Apotex Corp.*, C.A. No. 14-1038 (D. Del).

VENUE

13. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

THE '524 PATENT

14. The '524 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on May 21, 2013 to inventors Laurent D. Courvoisier, Robert E. McKean, and Hans-Joachim Jänsch.

15. The named inventors of the '524 patent assigned their rights in the '524 patent to Cephalon.

16. Cephalon is the sole owner by assignment of all rights, title and interest in the '524 patent.

17. The '524 patent is listed in FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") with respect to TREANDA[®].

18. The '524 patent will expire on March 26, 2029.

19. A true and accurate copy of the '524 patent is attached hereto as Exhibit A.

THE '190 PATENT

20. The '190 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on May 7, 2013 to inventors Jason Edward Brittain and Joe Craig Franklin.

21. The named inventors of the '190 patent assigned their rights in the '190 patent to Cephalon.

22. Cephalon is the sole owner by assignment of all rights, title and interest in the '190 patent.

23. The '190 patent is listed in the Orange Book with respect to TREANDA[®].

24. The '190 patent will expire on October 26, 2030.

25. A true and accurate copy of the '190 patent is attached hereto as Exhibit B.

THE '863 PATENT

26. The '863 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on December 17, 2013 to inventors Jason Edward Brittain and Joe Craig Franklin.

27. The named inventors of the '863 patent assigned their rights in the '863 patent to Cephalon.

28. Cephalon is the sole owner by assignment of all rights, title and interest in the '863 patent.

29. The '863 patent is listed in the Orange Book with respect to TREANDA[®].

30. The '863 patent will expire on January 12, 2026.

31. A true and accurate copy of the '863 patent is attached hereto as Exhibit C.

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